



K032833

**510(k) SUMMARY  
of  
SAFETY and EFFECTIVENESS**

**QUALITY FOR LIFE**

**A. General Information**

1. *Submitter's Name:* Otto Bock Health Care, LP
2. *Address:* Two Carlson Parkway, Suite 100  
Minneapolis, MN 55447-4467
3. *Telephone:* 763-553-9464
4. *Contact Person:* Bert Harman
5. *Date Prepared:* June 25, 2003
6. *Registration Number:* 2182293

North American Headquarters  
Two Carlson Parkway N., Suite 1C  
Minneapolis, MN 55447-4467  
Phone 1.800.328.4058  
Fax 1.800.655.4963

Customer Support &  
Distribution Center  
14630 28<sup>th</sup> Avenue North  
Minneapolis, MN 55447-4821  
Phone 1.800.328.4058  
Fax 1.800.962.2549

Technical Center  
14800 28<sup>th</sup> Avenue North, Suite 1  
Minneapolis, MN 55447-4873  
Phone 1.800.795.8846  
Fax 1.800.810.7994

Florida Area Fabrication Center  
755 Clay Street  
Winter Park, FL 32789  
Phone 1.800.354.5418  
Fax 1.407.599.7999

Ohio Area Fabrication Center  
84 Westpark Road  
Centerville, OH 45459  
Phone 1.937.432.0082  
Fax 1.937.432.0087

Utah Design &  
Manufacturing Center  
3820 W. Great Lakes Drive  
Salt Lake City, UT 84120-7205  
Phone 1.801.956.2400  
Fax 1.801.956.2401

Minnesota Design &  
Manufacturing Center  
820 Sundial Drive  
Waite Park, MN 56387  
Phone 1.800.688.4832  
Fax 1.320.251.0110

Customer Satisfaction Hotline  
1.877.OBSOLVE  
1.877.627.6583

[www.ottobockus.com](http://www.ottobockus.com)

**B. Device**

1. *Name:* MyoSystem with Customizing
2. *Trade Name:* MyoSystem with Customizing
3. *Common Name:* MyoSystem with Customizing
4. *Classification Name:* External Limb Prosthetic Component
5. *Product Code:* 6X4  
11 (2)
6. *Class:* 882.1320
7. *Regulation Number:*

**C. Identification of Legally Marketed Devices**

1. *Name:* MyoSystem
2. *K Number:* Exempt
3. *Date Cleared:* Exempt

#### **D. Description of the Device**

The MyoSystem with Customizing is an adult external electric upper extremity system which allows the CPO to adjust all relevant parameters of the control of an external powered upper extremity prosthesis by a Personal Computer (PC).

The system allows the connection of the control of a prosthesis with a PC by serial communication. A PC Software program allows the monitoring of how the patient performs with the prosthesis and enables the practitioner to change the control parameters according to the patient's needs.

In addition, the practitioner can do the same program changes between control programs of a component as he/she can do by changing a colored coding plug. As it is a much faster process to change a program by the click of a button rather than to dismantle the prosthesis to gain access to the coding plug of a component, there is less disruption in the fitting process. This makes it less tiring for the patient and practitioner.

As this system allows only additional adjustments to the existing adjustment possibilities by dials, there is no program change in the components. The same components which are used by the current conventional adjustment process are used with the adjustment process by CUSTOMIZING.

The MyoSystem with Customizing is composed of the following parts:

|  |               |
|--|---------------|
| <b>MyoBoy</b>                              | 757M10        |
| MyoBoy, Test adapter, Infrared cable       | 757P23        |
| <b>MyoBock System</b>                      |               |
| EnergyPack                                 | 757B20        |
| Li-Ion battery charger                     | 757L20        |
| System Electric Greifer DMC plus           | 8E33=8X047108 |
| <br>                                       |               |
| Electric wrist rotator                     | 10S17         |
| Ergo arm electronic plus                   | 12K50=50-1    |
| SensorHand                                 | 8E38=5-L7¾    |
| Transcarpal Hand Digital Twin              | 8E44=7-L7¾    |
| Four channel processor II                  | 13E195        |
| Adjustment cap                             | 13E196        |
| 2 x Myobock-Elektrode 228 (Electrode 60Hz) | 13E125=60     |
| 2 x Myobock-Elektrode 392 (Electrode 60Hz) | 13E68=60      |
| Distributor                                | 13E68190      |
| Battery connection cable                   | 13E188=200    |
| Coaxial plug                               | 9E169         |

|  |                        |
|--|------------------------|
| 3 x Electrode cable for 13E68                                  | 3E48=G800              |
| Electrode cable for 13E125                                     | 3E129=G1000            |
| Lamination ring  | 10S1=50                |
| Coding Plug set  | 13E182                 |
| Coupling piece   | none                   |
| Battery mounting set   | 757Z184=1              |
| <b>MyoCom</b>  | 757T11                 |
| MyoCom hardware  | 757T9                  |
| Myo simulator  | 757T10                 |
| Light wave cable   | 519K27=430             |
| Serial port converter  | 519K28                 |
| PC adaptor   | none                   |
| Connection cable MyoCom-MyoBoy                                 | 757P37                 |
| Connection cable MyoCom-battery mounting set                   | 757P38                 |
| Battery mounting set for EnergyPack                            | 757B20                 |
| Battery mounting set for EnergyPack                            | 757P21                 |
| <b>Software / Instructions / Manuals / Customizing</b>         |                        |
| <u>Product Component</u>                                       | <u>Revision</u>        |
| Myo Soft   | Rev. 1222H, Update     |
|  | Rev. 1222K             |
| Myosoft Customizing  | Rev. 1.0, Rev. 2.X     |
| Customizing  | Rev. D1 (Beta-review), |
|  | Rev. 2.0.3, Rev.2.1.1  |
| Training Instructions Customizing<br>(Powerpoint presentation) |                        |

#### **E. Intended Use Statement**

The MyoSystem with Customizing is intended for adult(s) who require an external electric upper extremity system.

#### **F. Technological Characteristics Summary**

The MyoSystem with Customizing is substantially equivalent to Otto Bock's MyoSystem, a Class I Exempt Device according to 21 CFR Part 890.3420.

Differences that exist between these devices, relating to technical specifications, physical appearance and design, do not affect the relative safety and effectiveness of the MyoSystem with Customizing.



JUN - 3 2010

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Otto Block Health Care, LP  
% Mr. Bert Herman  
2 Carlson Pkwy. Suite 100  
Minneapolis, Minnesota 55447

Re: K032833

Trade/Device Name: Myosystem with Customizing  
Regulation Number: 21 CFR 882.1320  
Regulation Name: Cutaneous Electrode  
Regulatory Class: Class II  
Product Code: GXY, IQZ  
Dated: June 25, 2003  
Received: September 11, 2003

Dear Mr. Herman:

This letter corrects our substantially equivalent letter of September 23, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 - Mr. Bert Herman

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a small "for" written below the signature.

Mark N. Melkerson

Director

Division of Surgical, Orthopedic,  
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

510(k) Number: K032833

Device Name: MyoSystem with Customizing

Indications for Use:

- Adult External Electric Upper Extremity System

PLEASE DO NOT WRITE BELOW THIS LINE --  
CONTINUE ON ANOTHER PAGE IF NEEDED


---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

OR

OVER-THE-COUNTER USE \_\_\_\_\_  
(optional Form 1-2-96)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K032833